

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH CAROLINA  
BEAUFORT DIVISION**

|                                               |   |                                         |
|-----------------------------------------------|---|-----------------------------------------|
| United States of America, <i>et al.</i> ,     | ) | Civil Action No. 9:14-cv-00230-RMG      |
|                                               | ) | (Consolidated with 9:11-cv-1593-RMG and |
| Plaintiffs,                                   | ) | 9:15-cv-2458-RMG)                       |
|                                               | ) |                                         |
| <i>ex rel.</i> Scarlett Lutz, <i>et al.</i> , | ) |                                         |
|                                               | ) |                                         |
| Plaintiffs-Relators,                          | ) |                                         |
|                                               | ) |                                         |
| v.                                            | ) |                                         |
|                                               | ) |                                         |
| Berkeley Heartlab, Inc., <i>et al.</i> ,      | ) |                                         |
|                                               | ) |                                         |
| Defendants.                                   | ) |                                         |
|                                               | ) |                                         |

**ORDER and OPINION**

This matter is before the Court on the United States' Objections to the BlueWave Defendants' Deposition Designations for the United States' 30(b)(6) witnesses Jennifer Williams and Michael Handrigan. (Dkt. Nos. 801-1, 803-1, 817-1.) The Court has ruled on each Objection as set forth below.

**I. Deposition of Jennifer Williams (Dkt. No. 818-2)**

| <b>BlueWave's Designation</b>   | <b>Government's Objection</b>                                                                                                                                                                                                                              | <b>Ruling</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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| Pg. 75, Ln. 22 – Pg. 76, Ln. 12 | Beyond the scope; seeks a legal conclusion; calls for speculation. The deponent is asked about HHS-OIG's position regarding a particular hypothetical arrangement, an issue for which this deponent was not designated and which seeks a legal conclusion. | The objection is overruled. Deponent was asked if "OIG take[s] the position that if a doctor chooses not to bill Medicare for a specimen collection fee, that the doctor can receive a payment from a lab for the same." Deponent was designated to speak about "Identification and explanation of past federal government guidance, issued by the Department of Health and Human Services Office of Inspector General (HHS-OIG) through June 25, 2014, such as relevant rules and regulations, Advisory Opinions, |

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|                                 |                                                                                                                                                                                                                                                                                              | <p>and Special Fraud Alerts on the definition of “commercial reasonableness” as those terms are used in the AKA and its exceptions and safe harbors.” (Dkt. No. 815-4 at 1, 4.) The question at issue is arguably relevant to OIG’s interpretation of commercial reasonableness so is not outside the scope of the designation.</p> <p>Deponent answered that OIG would assess such arrangements on a case by case basis, so the question did not lead the deponent to offer a legal conclusion or to speculate.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Pg. 89, Ln. 2 – Pg. 101, Ln. 16 | <p>Beyond the scope; counsel testifying (e.g., Pg. 90, Ln: 12-18; Pg. 92, Ln. 1-11; Pg. 101, Ln. 2-8); seeks a legal conclusion (e.g., Pg. 94, Ln. 1-4); calls for speculation (see id.); vague (e.g., Pg. 96, Ln. 22–Pg. 97, Ln. 5); best evidence (e.g., Pg. 98, Ln: 4-12); incomplete</p> | <p>The Government’s objections as to Pg. 90, Ln. 12-18; Pg. 92, Ln. 1-11; and Pg. 101, Ln. 2-8 are sustained because counsel is testifying.</p> <p>The Government’s objection that certain testimony (Pg. 94, Ln. 1-4) seeks a legal conclusion and calls for speculation is overruled. The question did not seek an inappropriate legal conclusion but asked directly about the scope of a safe harbor provision.</p> <p>The Government’s objection as to vagueness is overruled because counsel asked the question again later in the excerpt to clarify.</p> <p>The Government’s best evidence objection is overruled because the Court understands that the original or a duplicate copy of the document at issue will be introduced into evidence consistent with Federal Rules of Evidence 1002 and 1003.</p> <p>The objection is overruled as to completeness. The Government’s counter-designation resolves incompleteness [Pg. 101, Ln. 17 – Pg. 102, Ln. 11], and Defendants have not</p> |

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|                                   |                                                                                                                                                      | objected to the counter-designation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Pg. 103, Ln. 13 – Pg. 104, Ln. 11 | Relevance                                                                                                                                            | The objection is overruled. This designation is generally relevant to the issues in this case.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Pg. 106, Ln: 3 – Pg.: 110, Ln: 12 | Relevance (e.g., Pg. 106, Ln. 3-16); counsel testifying (e.g., Pg. 108, Ln. 5—Pg. 109, Ln.8); seeks a legal conclusion (see id.)                     | The Government's objection as to relevance is overruled because the deponent indicated that the advisory opinion language he was asked about has been changed, and the language in the document and subsequent changes may be relevant to this case.<br><br>The Government's objection that counsel is testifying or seeking a legal conclusion at Pg. 108, Ln. 5 – Pg. 109, Ln. 8 is overruled because counsel is asking about the meaning of the document which was within the scope of the designation, and counsel did not inappropriately testify or seek a legal conclusion when he read small excerpts of the document out loud to the deponent. |
| Pg. 118, Ln. 9 – Pg.: 119, Ln. 10 | Lacks foundation; best evidence                                                                                                                      | The Government's best evidence objection is overruled because the Court understands that the original or a duplicate copy of the document at issue will be introduced into evidence consistent with Federal Rules of Evidence 1002 and 1003.<br><br>The Government's objection that the testimony lacks foundation is overruled because counsel presented a direct question about the topic of a document and deponent answered. No additional foundation is required.                                                                                                                                                                                  |
| Pg. 119, Ln. 22 – Pg.: 123, Ln. 3 | Best evidence; calls for speculation (e.g., Pg. 121, Ln. 21—Pg. 122, Ln. 4); argumentative; counsel testifying (e.g., Pg. 122, Ln. 9—Pg. 123, Ln. 1) | The objection is sustained as to Pg. 121, Ln 21 – Pg. 122, Ln 4. The question is outside the scope of the designation. Deponent was not designated to speak generally about the difference between independent contractors and employees in terms of how easy it is to fire one or the other.                                                                                                                                                                                                                                                                                                                                                           |

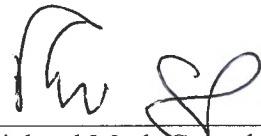
|                                   |                  |                                                                                                                                                                                                                                                                                                                                                                                                                       |
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|                                   |                  | <p>The Government's objection is overruled as to Counsel's question at Pg. 122, Ln. 9 – Pg. 123, Ln. 1. Counsel asked whether two situations described in advisory opinions are comparable and deponent confirmed that counsel's understanding of their similarity is correct. The line of questioning was not argumentative.</p>                                                                                     |
| Pg. 132, Ln. 16 – Pg. 133, Ln. 18 | Beyond the scope | <p>The objection is sustained. Deponent was designated to speak about specific HHS-OIG documents, but was not designated to speak to the entire universe of guidance. (Dkt. No. 815-4 at 1, 6 (Topics 12 and 13).) Deponent was asked if she knew of any other published guidance from OIG that covered the routine waiver of co-payments and deductibles. The question was outside the scope of the designation.</p> |
| Pg. 134, Ln. 16 – 21              | Relevance        | <p>The objection is sustained. The question and answer in this portion of the deposition transcript have no relevance to any issue in the case as excerpted. Deponent is asked if she reviewed two exhibit settlement agreements and responds in the affirmative. This information standing alone will not help the fact-finder.</p>                                                                                  |

**II. Deposition of Michael Handrigan (Dkt. No. 728-11 at 43-44)**

| BlueWave's Designation           | Government's Objections                                                                                                                                                                        | Ruling                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
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| Pg. 169, Ln. 4 – Pg. 170, Ln. 22 | Beyond the scope; calls for speculation. Deponent is asked for the policy behind Medicare's copay and deductible policy, a topic for which the deponent was not designated.                    | The objection is sustained in part and overruled in part. Deponent was designated to speak about "CMS processes, protocols and guidelines for approving lab test and/or testing services as eligible for payment by federal health care programs." (Dkt. No. 815-4 at 1, 7 (Topic 14).) Questions from Pg. 164, Ln. 4 through Pg. 170, Ln. 17 are within the scope of this designation. (Dkt. No. 728-11 at 43.) Deponent was then asked "do you know why the government or CMS takes the position that co-pays or deductibles are not applicable to lab tests." ( <i>Id.</i> ) Deponent represented that he did not know the answer to the question, and the question was beyond the scope of his designation. The Government's objection is therefore sustained for Pg. 170, Ln. 18 through 22. The Government's objection is otherwise overruled. |
| Pg. 171, Ln. 10-17               | Beyond the scope; not relevant. The deponent is asked about claims for services not provided, a topic for which the deponent was not designated and a matter that is not at issue in the case. | The objection is overruled. Deponent was designated to speak about "HDL's and Singulex claims for payment to the Medicare and Tricare programs" and "how HDL's and Singulex's claims to Medicare and TRICARE including the claims which are the subject of this complaint, were reviewed, denied and/or paid." (Dkt. No. 815-4 at 1, 7 (Topic 15).) Deponent was asked if he was aware of any claims that were made for services that were not performed. (Dkt. No. 728-11 at 43.) This question is arguably within the scope of Topic 15.<br><br>The Government also argues that this                                                                                                                                                                                                                                                               |

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|  | <p>question concerns a matter that is not at issue in this case, namely, whether any claims were made for services that were not provided. The Government has alleged that claims were submitted for services that were not medically necessary or that claims resulted from illegal kickbacks disguised as process and handling fees. Defendants intend to argue as a defense that the tests were medically necessary, so they have the right to present the jury with evidence that the tests were actually performed to bolster their defense that the claims submitted were legitimate, even if the Government does not argue that the services were not performed.</p> |
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**AND IT IS SO ORDERED.**



Richard Mark Gergel  
United States District Court Judge

January 12, 2017  
Charleston, South Carolina